IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 12-393-LPS
PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC.,	)	
Defendants.	)	

DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.'S ANSWER AND COUNTERCLAIM

Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"), answer the Complaint of Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon") as follows:

THE PARTIES

1. Plaintiff Horizon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and therefore denies them.

2. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1033 Skokie Boulevard, Suite 355, Northbrook, Illinois 60062.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

Answer: Par admits the allegations in paragraph 3 of the Complaint.

4. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977, and is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

Answer: Par admits the allegations in paragraph 4 of the Complaint.

5. Upon information and belief, Par Pharmaceutical, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

Answer: Par states that Par Pharmaceutical, Inc. is in the business of, among other activities, offering for sale, selling and/or importing branded and generic pharmaceutical products. Many of those products are sold, directly or indirectly, throughout the United States, including in the State of Delaware. To the extent there are any remaining allegations in paragraph 5 of the Complaint, Par denies them.

6. Upon information and belief, Par Pharmaceutical, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Par Pharmaceutical Companies, Inc.

Answer: Par states that Par Pharmaceutical, Inc. makes regulatory submissions to the FDA. Par denies the remaining allegations in paragraph 6 of the Complaint.

7. Upon information and belief, Par Pharmaceutical Companies, Inc. markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical Companies, Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Par Pharmaceutical Companies, Inc. controls and dominates Par Pharmaceutical, Inc., and thus the activities of Par Pharmaceutical, Inc. in this judicial district are attributable to Par Pharmaceutical Companies, Inc.

Answer: Par denies the allegations in paragraph 7 of the Complaint.

8. On information and belief, Par Pharmaceutical, Inc. alone and through its parent Par Pharmaceutical Companies, Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical, Inc. has engaged in systematic and continuous business within this judicial district.

Answer: Par states that Par Pharmaceutical, Inc., among other things, markets and sells branded and generic drugs, many of which are sold, directly or indirectly, throughout the United States, and within this judicial district. Par denies the remaining allegations in paragraph 8 of the Complaint.

9. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. collaborated in the research and development of Par's Abbreviated New Drug Application ("ANDA") No. 203658 for tablets that contain 800 mg of ibuprofen and 26.6 mg of famotidine as active ingredients ("the Par ANDA Product"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Par ANDA Product throughout the United States, including in the State of Delaware, in the event the FDA approves Par's ANDA.

Answer: Par denies the allegations in paragraph 9 of the Complaint.

JURISDICTION AND VENUE

10. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent No. 8,067,033 ("the '033 patent"). This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

Answer: Par admits that Horizon purports to bring this action under the patent laws of the United States. Par denies that Horizon properly states a claim for patent infringement. Par further states that it does not contest subject matter jurisdiction.

11. Upon information and belief, Par Pharmaceutical Companies, Inc. is subject to personal jurisdiction in this judicial district because it is incorporated in this State and it has purposely availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district.

Answer: Par states that it does not contest this Court's personal jurisdiction over Par Pharmaceutical Companies, Inc. for purposes of this action.

12. Upon information and belief, Par Pharmaceutical, Inc. is subject to personal jurisdiction in this judicial district because, inter alia, Par Pharmaceutical, Inc. is incorporated in this state, and Par Pharmaceutical, Inc., alone and through its parent Par Pharmaceutical Companies, Inc., has purposely availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district.

Answer: Par states that it does not contest this Court's personal jurisdiction over Par Pharmaceutical, Inc. for purposes of this action. Par denies any characterization of the

relationship between Par Pharmaceutical, Inc. and its parent, Par Pharmaceutical Companies, Inc. as stated or implied in paragraph 12 of the Complaint.

13. Upon information and belief, Par Pharmaceutical Companies, Inc. and/or Par Pharmaceutical, Inc. did not object to personal jurisdiction or venue in this judicial district in Civil Action Nos. 09-305-JJF, 09-481-LDD, 11-107-SLR, and 11-705-LPS.

Answer: Par admits the allegations in paragraph 13 of the Complaint.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

Answer: Par states that it does not contest venue in this judicial district for purposes of this action.

BACKGROUND

15. Horizon Pharma, Inc. is the holder of the approved New Drug Application ("NDA") No. 022519 for Duexis® tablets, which contains 26.6 mg of famotidine and 800 mg of ibuprofen as active ingredients. Duexis® was approved by the FDA on April 23, 2011, for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

Answer: Par states that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for NDA No. 022519 lists "Horizon Pharma" as the applicant. Par further states that the Orange Book entry for NDA No. 022519 lists the FDA approval date as April 23, 2011. Par further states that the labeling for Duexis® currently states that Duexis® is "indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patients who are taking ibuprofen

for those indications." To the extent that paragraph 15 of the Complaint contains additional allegations, Par denies them.

16. On information and belief, Par Pharmaceutical, Inc. submitted ANDA No. 203658 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic copies of Duexis® tablets.

Answer: Par admits that Par Pharmaceutical, Inc. submitted ANDA No. 203658 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg). To the extent that paragraph 16 of the Complaint contains additional allegations, Par denies them.

17. Upon information and belief, the Par ANDA Product that is the subject of Par's ANDA No. 203658 are tablets containing 800 mg of ibuprofen and 26.6 mg of famotidine as active ingredients, for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

Answer: Par states that the product that is the subject of ANDA No. 203658 is famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg). Par further states that ANDA No. 203658 currently includes proposed labeling that recites the indication "for the relief of signs and symptoms of rheumatoid arthritis and osteroarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications." To the extent that paragraph 17 of the Complaint contains additional allegations, Par denies them.

THE PATENTS-IN-SUIT

18. On November 29, 2011, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '033 patent titled "Stable Compositions of Famotidine and Ibuprofen." A true and correct copy of the '033 patent is attached hereto as Exhibit A.

Answer: Par admits that the '033 patent was issued on November 29, 2011, is entitled "Stable Compositions of Famotidine and Ibuprofen," and what appears to be a copy of the '033 patent is attached as Exhibit A to the Complaint. Par denies that the '033 was duly and legally issued.

19. Horizon Pharma USA, Inc. is the sole owner of the '033 patent.

Answer: Par states that the PTO assignment database lists Horizon Pharma USA, Inc. as the assignee of the '033 patent. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the Complaint and therefore denies them.

20. The '033 patent discloses and claims, inter alia, a pharmaceutical composition containing famotidine and ibuprofen.

Answer: Par states that the '033 patent disclosures and claims speak for themselves. Par specifically denies that the '033 patent claims "a pharmaceutical composition containing famotidine and ibuprofen."

21. The '033 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to Duexis®.

Answer: Par admits the allegations in paragraph 21 of the Complaint. Par further states that Horizon caused the '033 patent to be listed in the Orange Book relative to Duexis® by filing

a declaration with the FDA, and that the FDA published the '033 patent information in the Orange Book as a ministerial act.

22. The '033 patent covers the Duexis® product.

Answer: Par is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint and therefore denies them.

COUNT I FOR PATENT INFRINGEMENT

(Infringement of the '033 patent under 35 U.S.C. § 271(e)(2))

23. Horizon incorporates paragraphs 1-21 of this Complaint as if fully set forth herein.

Answer: Par incorporates herein its responses to the allegations in paragraphs 1-22 of the Complaint.

24. Upon information and belief, Par Pharmaceutical, Inc. sent a letter dated February 14, 2012, to Horizon Pharma, Inc. and Horizon Pharma USA, Inc., which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter advised Horizon that Par's ANDA contains a Paragraph IV certification with respect to the '033 patent, and that no valid, enforceable claim of the '033 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Par ANDA Product.

Answer: Par admits that Par Pharmaceutical, Inc. sent a letter dated February 14, 2012 to Horizon pursuant to 21 U.S.C. § 355(j)(2)(B), and states that the letter fully complied with the provisions of that statute. Par states that the letter, with its 22 pages of disclosure, speaks for itself, and that the letter advised Horizon that ANDA No. 203658 contains a Paragraph IV certification with respect to the '033 patent and that the letter further advised Horizon, *inter alia*, that the '033 patent is "invalid, unenforceable and/or will not be infringed" by manufacture,

importation, use, sale or offer for sale of the product that is the subject of ANDA No. 203658. To the extent that paragraph 24 of the Complaint contains additional allegations, Par denies them.

25. Upon information and belief, Par Pharmaceutical, Inc. submitted Par's ANDA No. 203658 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the Duexis® product prior to the expiration of the '033 patent.

Answer: Par states that Par Pharmaceutical, Inc. submitted ANDA No. 203658 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg) prior to the expiration of the '033 patent. To the extent that paragraph 25 of the Complaint contains additional allegations, Par denies them.

26. Upon information and belief, Par's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that, in its opinion, the '033 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Par ANDA Product.

Answer: Par states that ANDA No. 203658 contains a Paragraph IV Certification asserting that, in Par Pharmaceutical, Inc.'s opinion, the '033 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the product that is the subject of ANDA No. 203658. To the extent that paragraph 26 of the Complaint contains additional allegations, Par denies them.

27. By filing Par's ANDA No. 203658 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or

importation of the Par ANDA Product prior to the expiration of the '033 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Par plans to commercially use, offer for sale, and/or sell the Par ANDA Product, and/or to induce or contribute to such activity, and by such actions Par would infringe one or more claims of the '033 patent under 35 U.S.C. § 271(a), (b) and/or (c).

Answer: Par denies the allegations in paragraph 27 of the Complaint.

28. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. participated in, contributed to, aided, and/or induced the submission of Par's ANDA No. 203658 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. will market and/or distribute the Par ANDA Product in the United States, and within this judicial district, if Par's ANDA No. 203658 is approved by the FDA. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. thus are jointly and severally liable for infringement of the '033 patent.

Answer: Par states that Par Pharmaceutical, Inc. submitted ANDA No. 203658 and its Paragraph IV certification to the FDA, and seeks FDA approval to market the product as defined in that ANDA. Par denies the remaining allegations in paragraph 28 of the Complaint.

29. This action is being filed within 45 days of receipt by Horizon of the Par letter dated February 14, 2012, which purportedly advised Horizon of Par's Paragraph IV Certification with respect to the '033 patent.

Answer: Par lacks knowledge or information sufficient to form a belief as to the allegations in paragraph 29 of the Complaint and therefore denies them.

30. Upon information and belief, Par had actual and constructive notice of the '033 patent prior to filing Par's ANDA No. 203658, and Par's infringement of the '033 patent has been, and continues to be, willful.

Answer: Par states that it was aware of the existence of the '033 patent prior to Par Pharmaceutical, Inc.'s filing of ANDA No. 203658. Par denies the remaining allegations in paragraph 30 of the Complaint.

31. Horizon is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 203658 be a date that is not earlier than the expiration of the '033 patent, or any later expiration of exclusivity for the '033 patent to which they become entitled.

Answer: Par denies the allegations in paragraph 31 of the Complaint.

32. Horizon will be irreparably harmed if Par is not enjoined from infringing or actively inducing or contributing to infringement of the '033 patent, as Horizon has no adequate remedy at law.

Answer: Par denies the allegations in paragraph 32 of the Complaint.

33. This is an exceptional case, and Horizon is entitled to its costs and reasonable attorney fees.

Answer: Par denies the allegations in paragraph 33 of the Complaint.

PRAYER FOR RELIEF

Par denies that Horizon is entitled to any of the relief it seeks in its Complaint.

AFFIRMATIVE DEFENSES

1. The claims of the '033 patent are invalid under 35 U.S.C. § 1 *et seq.* and/or the doctrine of obviousness-type double patenting.

2. Par Pharmaceutical, Inc.'s filing of ANDA No. 203658 was not an act of infringement of any claim of the '033 patent.

3. The manufacture, use, offer for sale, sale, marketing, distribution, or importation of the product that is the subject of Par Pharmaceutical, Inc.'s ANDA No. 203658 would not infringe any claim of the '033 patent.

4. The Complaint fails to state a claim for which relief can be granted.

5. The relief requested in the Complaint is barred by the doctrines of estoppel and/or waiver.

COUNTERCLAIM

Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"), assert the following Counterclaim against Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon"):

THE PARTIES

1. Par Pharmaceutical Companies, Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

3. Horizon Pharma, Inc. asserts in its Complaint that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

4. Horizon Pharma USA, Inc. asserts in its Complaint that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1033 Skokie Boulevard, Suite 355, Northbrook, Illinois 60062.

NATURE OF THE ACTION

5. Par seeks a declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent No. 8,067,033 is invalid and not infringed.

JURISDICTION

6. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Horizon based, *inter alia*, on the filing by Horizon of this lawsuit in this jurisdiction.

VENUE

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d), 1400(b), and Horizon's choice of forum.

BACKGROUND

9. U.S. Patent No. 8,067,033 (the "'033 patent") entitled "Stable Compositions of Famotidine and Ibuprofen" issued on November 29, 2011.

10. On information and belief, Horizon Pharma USA, Inc. is the assignee of the '033 patent.

11. On information and belief, Horizon Pharma, Inc. is the holder of New Drug Application No. 022519 ("NDA No. 022519") for famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg), marketed under the brand name Duexis®. In connection with

NDA No. 022519, Horizon Pharma, Inc. caused the U.S. Food and Drug Administration ("FDA") to list the '033 patent in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

12. Par Pharmaceutical, Inc. submitted to the FDA Abbreviated New Drug Application No. 203658 ("ANDA No. 203658") requesting regulatory approval to engage in the commercial manufacture, use, or sale of famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg) ("ANDA Famotidine and Ibuprofen Tablets") before the expiration of the Orange Book patents listed for Duexis®. Par Pharmaceutical, Inc. made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '033 patent listed in the Orange Book for Duexis® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Famotidine and Ibuprofen Tablets.

13. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on February 14, 2012, Par Pharmaceutical, Inc. notified Horizon of the paragraph IV certification filed with ANDA No. 203658 for the '033 patent. The notice set forth detailed bases for Par Pharmaceutical, Inc.'s opinion that the ANDA Famotidine and Ibuprofen Tablets do not infringe any claim of the '033 patent, and that the '033 patent claims are invalid and/or unenforceable. The notice also included an offer of confidential access to ANDA No. 203658.

14. On March 28, 2012, Horizon filed its Complaint alleging infringement of the '033 patent by Par.

15. Horizon did not accept Par Pharmaceutical, Inc.'s offer of confidential access to ANDA No. 203658, and did not obtain or review a copy of Par Pharmaceutical, Inc.'s ANDA No. 203658 before filing this action.

16. Upon information and belief, Horizon filed this action against Par notwithstanding the fact that it had notice that the subject ANDA Famotidine and Ibuprofen Tablets do not infringe any claim of the '033 patent.

COUNT ONE

(Declaratory Judgment regarding U.S. Patent No. 8,067,033)

17. Par realleges paragraphs 1-16 of the Counterclaim as if fully set forth herein.

18. The claims of the '033 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

19. Par Pharmaceutical, Inc.'s filing of ANDA No. 203658 did not infringe any valid claim of the '033 patent.

20. The commercial manufacture, use, offer for sale, sale, or importation of the ANDA Famotidine and Ibuprofen Tablets would not infringe any valid claim of the '033 patent.

21. An actual and justiciable controversy exists between the parties with respect to the '033 patent, and Par is entitled to a declaratory judgment that the '033 patent is invalid and not infringed.

22. This is an exceptional case, and Par is entitled to its costs and reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Horizon and grant the following relief:

A. Declare that the claims of the '033 patent are invalid;

B. Declare that Par Pharmaceutical, Inc.'s filing of ANDA No. 203658 was not an act of infringement of any claim of the '033 patent.

C. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of the ANDA Famotidine and Ibuprofen Tablets would not infringe the claims of the '033 patent;

D. Declare that this case is exceptional under 35 U.S.C. § 285;

E. Award Par its costs and reasonable attorney fees to the extent permitted by law; and

F. Award Par such other and further relief as the Court deems just and proper.

/s/ Steven J. Fineman

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